CLAIMS

What is claimed is:

1. A method of performing a clinical trial comprising: randomizing study participants into a plurality of treatment groups;

performing a first phase of testing, said first phase of testing including administering an active treatment to a first group of said plurality of treatment groups, and administering a placebo to a remainder of said treatment groups;

determining whether each participant in each of said treatments groups is a responder or a non-responder;

performing a second phase of testing, said second phase of testing including administering said placebo to at least one non-responder in at least one group, and administering said active treatment to at least one non-responder in at least one group; and

analyzing data from at least one of said first phase of testing and from said second phase of testing.

2. The method of claim 1 further comprising discontinuing treatment for responders in at least one of said plurality of groups.

3. The method of claim 1 further comprising entering open continuation therapy for responders in at least one of said plurality of groups.

4. The method of claim 1 wherein said treatments groups have the same number of study participants.

5. The method of claim 1 wherein at least two of said treatment groups have a different number of study participants.

6. The method of claim 1 wherein the clinical trial comprises a double-blind clinical trial.

7. The method of claim 1 wherein the treatment time for each of said plurality of groups is the same.

8. The method of claim 1 wherein the treatment time for the first phase and the second phase is the same.

9. The method of claim 1 wherein the treatment time for the first phase is different than the treatment time for the second phase.

10. The method of claim 1 wherein said active treatment corresponds to a drug treatment.

11. The method of claim 1 wherein said analyzing comprises determining an effect of active treatment.

12. The method of claim 1 wherein said analyzing comprises determining a placebo response rate.

13. The method of claim 11 wherein said determining an effect of active treatment is assessed using a z-score.

14. The method of claim 11 wherein said determining an effect of active treatment is performed in accordance with the formula:

$$h = w(p_1 - q_1) + (1\text{-}w)(p_2 - q_2)$$

wherein h is the effectiveness of the treatment, w is a weighting factor, p_1 is the response rate to the first administration of treatment, q_1 is the response rate to the first administration of placebo, p_2 is the response rate to the second administration of treatment, and q_2 is the response rate to the second administration of placebo.

15. The method of claim 11 wherein said determining an effect of active treatment is performed in accordance with the formula:

$$h = w\left(\frac{n_{3,1}}{n(1-2a)} - \frac{(n_{1,3}+n_{2,3})}{2na}\right) + (1-w)\left(\frac{n_{2,1}}{n_{2,1}+n_{2,2}} - \frac{n_{1,1}}{n_{1,1}+n_{1,2}}\right),$$

wherein h is the effectiveness of the treatment, w is a weighting factor, n is the total number of study participants, n is the total number of study participants, $n_{1,1}$ is the number of participants who were non-responders to placebo in the first phase and were responders to placebo in the second phase, $n_{1,2}$ is the number of participants who were non-responders to placebo in the first phase and were non-responders to placebo in the second phase, $n_{1,3}$ is the number of participants who were responders to placebo in the first phase and were responders to placebo in the second phase, $n_{2,1}$ is the number of participants who were non-responders to placebo in the first phase and were responders to treatment in the second phase, $n_{2,2}$ is the number of participants who were non-responders to placebo in the first phase and were non-responders to treatment in the second phase, $n_{2,3}$ is the number of participants who were responders to placebo in the first phase and were responders to treatment in the second phase, $n_{31,}$ is the number of participants who were responders to treatment in the first phase.

16. The method of claim 14 wherein data from said administering placebo to non-responders in said first group is not used in said determining said placebo response rate.

17. The method of claim 1 wherein said randomizing study participants into a plurality of treatment groups comprises randomizing said study participants into a first treatment group and a second treatment group.

18. The method of claim 17 further comprising randomizing said study participants into a third treatment group.

19. The method of claim 18 wherein said administering a placebo to a remainder of said treatment groups comprises administering said placebo to said second group of said plurality of treatment groups and administering said placebo to said third group of said plurality of treatment groups.

20. The method of claim 19 wherein said second phase of testing comprises administering said placebo to non-responders in said first group, administering said active treatment to non-

responders in said second group, and administering said placebo to non-responders in said third group.

21. The method of claim 19 further comprising entering open continuation therapy for responders in said first group, responders in said second group and responders in said third group.

22. The method of claim 19 wherein two of said three treatments groups has the same number of study participants.

23. The method of claim 19 wherein two of said three treatments groups has a different number of study participants.

24. The method of claim 19 wherein said randomizing study participants into three treatment groups is done in accordance with a ratio of 1-2a for said first group, a for said second group, and a for said third group.

25. A system for performing a clinical trial comprising:

a database including a listing of identified study participants for the clinical trial;

a first randomizer providing a plurality of randomized groups of study participants from said database of identified participants;

a first pool of study participants wherein a first group of randomized study participants selected from said first pool of study participants receive a first treatment and a remainder of said groups of randomized study participants of said first pool of study participants receive a second treatment, administration of said first treatment resulting in responders to said first treatment and non-responders to said first treatment, and administration of said second treatment resulting in responders to said second treatment and non-responders to said second treatment;

a second pool of study participants comprising non-responders to said first treatment and non-responders to said second treatment, wherein at least one non-responder to said second treatment receives said first treatment and at least one non-responder to said second treatment receives said second treatment; and

an analyzer wherein data from said first treatment and said second treatment are analyzed to provide a determination of effectiveness of said first treatment.

26. The system of claim 25 wherein said first treatment corresponds to an active treatment.

27. The system of claim 25 wherein said second treatment corresponds to a placebo.

28. The system of claim 25 further comprising a second randomizer for receiving information with respect to the non-responders to the second treatment and for randomizing non-responders to said second treatment into a third treatment group and a fourth treatment group.

29. A system for performing a clinical trial comprising:

means for randomizing study participants into a plurality of treatment groups;

means for performing a first phase of testing, said first phase of testing including administering an active treatment to a first group of said plurality of treatment groups and administering a placebo to a remainder of said treatment groups;

means for determining whether each subject in each of said treatments groups is a responder or a non-responder;

means for performing a second phase of testing, said second phase of testing including administering said placebo to non-responders in said first group, administering said active treatment to at least one non-responder in said remainder of treatment groups, and administering said placebo to at least one non-responders in said remainder of treatment group; and

means for analyzing data from at least one of said first phase of testing and from said second phase of testing.

30. The system of claim 29 further comprising means, coupled to said means for analyzing, for storing information related to the study participants.

31. The system of claim 29 wherein said means for analyzing comprises means for determining an effectiveness of said active treatment.

32. The system of claim 29 wherein said plurality of groups comprises a first treatment group and a second treatment group.

33. The system of claim 28 wherein said plurality of groups comprises a first treatment group, a second treatment group and a third treatment group.